TESTIMONY BY

VICTOR E. SCHWARTZ

GENERAL COUNSEL, AMERICAN TORT REFORM ASSOCIATION

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE HOUSE ENERGY AND COMMERCE COMMITTEE

UNITED STATES HOUSE OF REPRESENTATIVES

"CURRENT ISSUES RELATED TO MEDICAL LIABILITY REFORM"

on

THURSDAY, FEBRUARY 9, 2005

Chairman Deal, Ranking Member Brown, and Members of this Distinguished Subcommittee,

I thank you for your kind invitation to testify today about whether it is appropriate to preclude punitive damages from being awarded against manufacturers of medical products, when the products were subject to pre-market approval by the Food and Drug Administration (hereinafter "FDA").

Background

By way of background, the subject of tort law has been of interest to me throughout my career. I was a law professor and acting dean of the University of Cincinnati College of Law, and have taught at the University of Virginia, Georgetown, and American University Law Schools. I continue my affiliation with Cincinnati as an Adjunct Professor and a Member of the Board of Visitors.

I am co-author of *Prosser, Wade & Schwartz's Torts* (10th ed., 2000), the most widely used torts casebook in the United States. For the first fourteen years of my practice, I represented only injured persons and assisted in obtaining the first punitive damages verdict in the State of Ohio against a product manufacturer.

I have served under both President Ford and President Carter as Chair of the Federal Inter-Agency Task Force on Product Liability. That Task Force

explored the product liability crisis that arose in the late 1970s and 1980s. It also developed the Model Uniform Product Law Act, which has been used as a basis for state legislation and the development of law by courts. I have had the privilege of working with Members of Congress from both parties on numerous federal liability issues, including the successful enactment of the Biomaterials Assurance Access Act of 1998, the General Aviation Revitalization Act of 1994, and the Paul D. Coverdell Teacher Protection Act of 2001.

For the past two decades, I have worked at law firms whose principal practice has been on the defense side. Currently, I chair Shook, Hardy & Bacon's Public Policy Group. Approximately two hundred articles that I have authored or co-authored have been published in learned journals. I have been fortunate to have many of them cited by courts as a basis for rulings of law. I serve, and I am speaking today, as General Counsel to the American Tort Reform Association (hereinafter "ATRA"), but the views are solely my own, based on my practice and experience. No one, other than my Public Policy Group colleagues at Shook, Hardy & Bacon, has changed or modified my testimony.

History of Punitive Damages in a Nutshell

Punitive damages evolved in England in the development of common law. They served, and continue to serve, an important function. They were an auxiliary to the criminal law to help assure that persons who committed wrongful criminal acts paid a price for their conduct, even if the government did not

prosecute these acts. The purposes of punitive damages are to punish the defendant, deter him from committing future wrongful acts and to deter others who might be similarly inclined, so that such acts are less likely to occur in the future.

It should be absolutely clear to this Subcommittee that punitive damages are not compensatory. Compensatory damages include paying people for their out-of-pocket losses in the past and in the future, and also damages for pain and suffering, emotional loss, and other harms that do not readily translate to a precise monetary value.

Punitive damages are, in effect, punishment by the state. State means are used to enforce punitive damages, the same way state means are used to enforce the criminal law or government action and civil fines. As a practical matter, there is no difference. The state will use its official mechanisms to enforce such awards, and the sting is the same. Sometimes it is more so, because punitive damages – especially when they are large – generate quite a bit of publicity. Most constitutional rights that protect criminal defendants, however, do not apply to defendants who are subject to punitive damages. This is one basic reason why this body should work to assure that the punitive damages system is fair.

The Change in Punitive Damages

During oral argument of a major punitive damage case, *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), Justice Scalia asked a lawyer for a petitioner who was seeking to overturn a punitive damages award, "Who whispers in my ear what was constitutional in 1789 is not constitutional today?" I attended that argument and Justice Scalia, at least in my view, did not receive a clear answer to his question. Here is the answer.

In 1789, punitive damages were confined solely to purposeful, wrongful acts, such as battery, assault, and wrongful imprisonment. They also were never larger than compensatory awards, and usually less. They dealt with a wrongful act and were imposed once on a defendant. In the past three decades, punitive damages have undergone substantial change in all three of these areas. Punitive damages are not at all the same as they were in 1789.

First, the standard for awarding punitive damages has been attenuated in a number of states, and mere gross negligence as contrasted with purposeful conduct, could be a trigger for making an award. Second, the types of acts for which punitive damages may be imposed have become less clear and harder to define or predict. Finally, punitive damages awards might be awarded multiple times, especially against manufacturers where each plaintiff against the company may seek an award and a jury has absolutely no idea that awards were previously made.

This is by way of background to evaluate whether it is appropriate to allow the state to punish a defendant – who has marketed a drug or medical device, and has fully complied with FDA pre-market approval and post-market rules and regulations. Of course, every Member of this Subcommittee knows, and most Americans know, that the FDA and its procedures have been under question in recent times. Not long ago, I remember when the FDA was challenged because it was not moving quickly enough in providing the American public with drugs that were needed to fight serious diseases. Now, among many, there is a contrary feeling – that the FDA may be moving too quickly and not carefully enough in the drug approval process. That debate is an important one to have in Congress, but it is not relevant for a core public policy decision about whether someone should be punished who has complied with the law.

Let me give you an example. A number of years ago, Congress decided to allow states to raise the speed limit on automobile driving. My friend, Ralph Nader, and others, strongly decried the charge, stating that it would lead to more accidents and more fatalities. Nevertheless, it was the view of Congress that the states should be permitted to allow drivers to go drive much faster than 55 mph – 65, 75 or even 85 mph. Consider a motorist going 65 mph on a clear day that tries to drive carefully but nevertheless has a collision. The facts indicate that if he had been driving more slowly, he may have avoided an accident. In our legal system, that drive may be subject to civil liability. Rational thought clearly suggests, however, that a driver going at or below the legal speed limit should not

be punished by the state. If the law needs to change, this body or state legislature should do it. Punishment is not appropriate for totally lawful acts that have been specifically considered by Congress.

Even prominent members of the personal injury bar agree with this concept. For example, in a trip to Texas not long ago, I noticed advertisements on the highway, placed by the Texas Trial Lawyers Association, which is composed of some of the toughest, most effective personal injury lawyers in America. The advertisement stated, "Punitive damages are needed to punish corporate criminals." This may be true because law enforcement mechanisms are sometimes overwhelmed with more serious cases and do not have time to punish wrongful, criminal corporate acts. If a corporation has complied with the law, and a company that manufactures pharmaceuticals or medical devices has met the standards of pre-market approval for the FDA, it is difficult, as a matter of public policy, to see why they should be punished. If the FDA standard needs to be changed (just like the situation with the speed limit, which may need to be changed), it is the responsibility of this body to make the change. No matter how emotional the arguments might be, it is not sound public policy to punish a company that has complied with the legal rules.

Experience with FDA Compliance Punitive Damages Defense

Compliance with FDA standards defenses have been enacted in a number of states, including Arizona, Michigan, New Jersey, Oregon, Utah and Ohio

(copies of laws attached hereto). The Michigan law goes further than the bill you are considering – it provides that a product is not defective or unreasonably dangerous, and the manufacturer or seller is therefore not liable in a product liability action, if the product at issue was approved by the FDA for safety and efficacy.

I was personally involved in the development of the law in Ohio, which was enacted in 1987. Those who opposed it predicted that the drug companies might treat Ohio as part of Sodom and Gomorra and dump dangerous drugs in the state. They said drug warnings might disappear, and defective drugs would be heaped upon the good citizens of Ohio. As a member of the Ohio Bar, former dean and currently an Adjunct Professor at Cincinnati, I certainly did not wish to be part of such mayhem, but I believed, for the policy reasons I have outlined today, that punishment should not be imposed against people who follow the law. The FDA compliance punitive damages defense would be sound policy and do no harm. Well, that provision has now been law for more than 15 years. Recently, the issue was reviewed again by the Ohio legislature, and the legislation kept that law in place there has been not a scintilla of evidence that any wrongful conduct was caused by this defense. In fact, in December 2004, the Ohio legislature amended the law to extend the FDA compliance punitive damages defense to over-the-counter drugs and medical devices, in addition to prescription drugs.

Pharmaceutical companies in Ohio and a number of other states have been treated with fairness in not being subject to punishment when they follow the law. They still may be subject to liability for compensatory damages. In pharmaceutical cases, these damages are substantial, but they should not be punished.

The experience in Ohio can be revealing, because sometimes there may be factual questions as to whether a particular defendant withheld material information or made misrepresentations to the FDA regulators; in other words, a question of fact. When such an issue goes to a jury, it is told that punitive damages are not to be awarded if a company met the standards of pre-market approval and did not withhold material information or misrepresent the facts. What a jury sometimes hears is that it should award punitive damages if a defendant did not comply with FDA regulations. For that reason, in this type of defense there is a certain danger to companies who are reckless or negligent and fail to meet FDA requirements. It exerts a powerful pressure to follow the law.

Motivation is Not Simply by Sticks, but Carrots

Incentives to follow the law can be positive. Motivation is not brought about by sticks; carrots help too. In the past twenty years of practice, I have worked with pharmaceutical companies in a counseling role. I would share with you that a good, well-drafted FDA punitive damage defense can help bring about good conduct.

FDA rules sometimes are precise, but do leave room for judgment at times. When client conduct can be assured, going to the ultimate to meet every requirement and turn over all pertinent information to the FDA (such as adverse risk reports) will prevent punishment; it can be a factor in motivating conduct that is positive and goes far beyond the requirements of the black letter of the law. Life experience teaches us that carrots as well as sticks can motivate good results. A properly constructed FDA defense can do just that, a point that is overlooked or perhaps not appreciated by those who oppose such provisions because those opponents of a sound public policy idea are not and have not been in a position of providing counsel.

Conclusion

If one places the words "Food and Drug Administration" into Google™ on the Internet, hundreds of thousands of hits come up now because it is very controversial. This body can and will regulate FDA procedures and rules. What is important to appreciate today is that state punishment – and that is punitive damages – should be reserved for unlawful conduct. If a company in good faith comports with the rules and regulations, and meets the requirements of the organization established by federal law to govern its behavior, monitor it and review it on a national basis, punishment is totally and entirely inappropriate.

I thank you very much for your kind attention, and would be pleased to answer any questions.

APPENDIX:

STATE FDA REGULATORY

COMPLIANCE DEFENSE STATUTES

Arizona Revised Statutes Annotated

Title 12. Courts and Civil Proceedings

Chapter 6. Special Actions and Proceedings by Individual Persons

Article 11. Drugs and Pharmaceuticals

§ 12-701. Drugs; exemplary or punitive damages; definition

A. The manufacturer or seller of a drug is not liable for exemplary or punitive damages if the drug alleged to cause the harm either:

1. Was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal food and drug administration under the food, drug and cosmetic act (21 United States Code § 301, et seq.) or the public health service act (42 United States Code § 201, et seq.) or

2. Is generally recognized as safe and effective pursuant to conditions established by the federal food and drug administration and applicable regulations, including packaging and labeling regulations.

B. Subsection A does not apply if the plaintiff proves, by clear and convincing evidence, that the defendant, either before or after making the drug available for public use, knowingly, in violation of applicable federal food and drug administration regulations, withheld from or misrepresented to the administration information known to be material and relevant to the harm which the plaintiff allegedly suffered.

C. In this section, "drug" means the same as provided in § 201(g)(1) of the federal food, drug and cosmetic act (21 United States Code § 321(g)(1)).

CREDIT(S)
Added by Laws 1989, Ch. 172, § 1.

Michigan Compiled Laws Annotated

Chapter 600. Revised Judicature Act of 1961

Revised Judicature Act of 1961

Chapter 29. Provisions Concerning Specific Actions

600.2946. Product liability actions, admissibility of evidence; liability, burden of proof; presumption; drugs

Sec. 2946. (1) It shall be admissible as evidence in a product liability action that the production of the product was in accordance with the generally recognized

and prevailing nongovernmental standards in existence at the time the specific unit of the product was sold or delivered by the defendant to the initial purchaser or user.

(2) In a product liability action brought against a manufacturer or seller for harm allegedly caused by a production defect, the manufacturer or seller is not liable unless the plaintiff establishes that the product was not reasonably safe at the time the specific unit of the product left the control of the manufacturer or seller and that, according to generally accepted production practices at the time the specific unit of the product left the control of the manufacturer or seller, a practical and technically feasible alternative production practice was available that would have prevented the harm without significantly impairing the usefulness or desirability of the product to users and without creating equal or greater risk of harm to others. An alternative production practice is practical and feasible only if the technical, medical, or scientific knowledge relating to production of the product, at the time the specific unit of the product left the control of the manufacturer or seller, was developed, available, and capable of use in the production of the product and was economically feasible for use by the manufacturer. Technical, medical, or scientific knowledge is not economically feasible for use by the manufacturer if use of that knowledge in production of the product would significantly compromise the product's usefulness or desirability.

(3) With regard to the production of a product that is the subject of a product liability action, evidence of a philosophy, theory, knowledge, technique, or procedure that is learned, placed in use, or discontinued after the event resulting in the death of the person or injury to the person or property, which if learned, placed in use, or discontinued before the event would have made the event less likely to occur, is admissible only for the purpose of proving the feasibility of precautions, if controverted, or for impeachment.

(4) In a product liability action brought against a manufacturer or seller for harm allegedly caused by a product, there is a rebuttable presumption that the manufacturer or seller is not liable if, at the time the specific unit of the product was sold or delivered to the initial purchaser or user, the aspect of the product that allegedly caused the harm was in compliance with standards relevant to the event causing the death or injury set forth in a federal or state statute or was approved by, or was in compliance with regulations or standards relevant to the event causing the death or injury promulgated by, a federal or state agency responsible for reviewing the safety of the product. Noncompliance with a standard relevant to the event causing the death or injury set forth in a federal or state statute or lack of approval by, or noncompliance with regulations or standards relevant to the event causing the death or injury promulgated by, a federal or state agency does not raise a presumption of negligence on the part of a manufacturer or seller. Evidence of compliance or noncompliance with a

regulation or standard not relevant to the event causing the death or injury is not admissible.

(5) In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. However, this subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval. This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:

(a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act, chapter 675, 52 Stat. 1040, 21 U.S.C. 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360, 360b to 376, and 378 to 395, and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

(b) Makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug.

CREDIT(S)
Amended by P.A.1995, No. 249, § 1, Eff. March 28, 1996.

New Jersey Statutes Annotated
Title 2A. Administration of Civil and Criminal Justice
Subtitle 6. Specific Civil Actions
Chapter 58C. Products Liability

→2A:58C-5. Punitive damages

a. (Deleted by amendment, P.L.1995, c. 142.)

b. (Deleted by amendment, P.L.1995, c. 142.)

c. Punitive damages shall not be awarded if a drug or device or food or food additive which caused the claimant's harm was subject to premarket approval or

licensure by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201 et seq. and was approved or licensed; or is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations. However, where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question, punitive damages may be awarded. For purposes of this subsection, the terms "drug", "device", "food", and "food additive" have the meanings defined in the "Federal Food, Drug, and Cosmetic Act."

d. (Deleted by amendment, P.L.1995, c. 142.)

CREDIT(S)
L.1987, c. 197, § 5, eff. July 22, 1987. Amended by L.1995, c. 142, § 8.

Baldwin's Ohio Revised Code Annotated

Title XXIII. Courts--Common Pleas
Chapter 2307. Civil Actions
Product Liability Claims
2307.80 Effect of recall notification

Underlines and strikethroughs represent amendments enacted in 2004 in 2004 Ohio Laws File 144 (S.B. 80) (Am. Sub. S.B. 80). The changes are effective on April 7, 2005.

(A) Subject to ~~division~~ divisions (C) and (D) of this section, punitive or exemplary damages shall not be awarded against a manufacturer or supplier in question in connection with a product liability claim unless the claimant establishes, by clear and convincing evidence, that harm for which the claimant is entitled to recover compensatory damages in accordance with section 2307.73 or 2307.78 of the Revised Code was the result of misconduct of the manufacturer or supplier in question that manifested a flagrant disregard of the safety of persons who might be harmed by the product in question. The fact by itself that a product is defective does not establish a flagrant disregard of the safety of persons who might be harmed by that product.

(B) Whether the trier of fact is a jury or the court, if the trier of fact determines that a manufacturer or supplier in question is liable for punitive or exemplary damages in connection with a product liability claim, the amount of those damages shall be determined by the court. In determining the amount of punitive

or exemplary damages, the court shall consider factors including, but not limited to, the following:

(1) The likelihood that serious harm would arise from the misconduct of the manufacturer or supplier in question;

(2) The degree of the awareness of the manufacturer or supplier in question of that likelihood;

(3) The profitability of the misconduct to the manufacturer or supplier in question;

(4) The duration of the misconduct and any concealment of it by the manufacturer or supplier in question;

(5) The attitude and conduct of the manufacturer or supplier in question upon the discovery of the misconduct and whether the misconduct has terminated;

(6) The financial condition of the manufacturer or supplier in question;

(7) The total effect of other punishment imposed or likely to be imposed upon the manufacturer or supplier in question as a result of the misconduct, including awards of punitive or exemplary damages to persons similarly situated to the claimant and the severity of criminal penalties to which the manufacturer or supplier in question has been or is likely to be subjected.

(C) ~~If~~ (1) Except as provided in division (C)(2) of this section, if a claimant alleges in a product liability claim that a drug or device caused harm to the claimant, the manufacturer of the drug or device shall not be liable for punitive or exemplary damages in connection with that product liability claim if the drug or device that allegedly caused the harm satisfies either of the following:

(a) It was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal food and drug administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C. 301-392, as amended, or the "Public Health Service Act," 58 Stat. 682 (1944), 42 U.S.C. 201-300cc-15, as amended~~, unless it is established~~.

(b) It was an over-the-counter drug marketed pursuant to federal regulations, was generally recognized as safe and effective and as not being misbranded pursuant to the applicable federal regulations, and satisfied in relevant and material respects each of the conditions contained in the applicable regulations and each of the conditions contained in an applicable monograph.

(2) Division (C)(1) of this section does not apply if the claimant establishes, by a preponderance of the evidence, that the manufacturer fraudulently and in violation of applicable regulations of the food and drug administration withheld from the food and drug administration information known to be material and

relevant to the harm that the claimant allegedly suffered or misrepresented to the food and drug administration information of that type. ~~For~~

(3) For purposes of ~~this division, "drug~~ divisions (C) and (D) of this section:

(a) "Drug" has the same meaning ~~given to that term~~ as in the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 1041 (1938), 21 U.S.C. 321(g)(1), as amended.

(b) "Device" has the same meaning as in the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 1041 (1938), 21 U.S.C. 321(h), as amended.

(D)(1) If a claimant alleges in a product liability claim that a product other than a drug or device caused harm to the claimant, the manufacturer or supplier of the product shall not be liable for punitive or exemplary damages in connection with the claim if the manufacturer or supplier fully complied with all applicable government safety and performance standards, whether or not designated as such by the government, relative to the product's manufacture or construction, the product's design or formulation, adequate warnings or instructions, and representations when the product left the control of the manufacturer or supplier, and the claimant's injury results from an alleged defect of a product's manufacture or construction, the product's design or formulation, adequate warnings or instructions, and representations for which there is an applicable government safety or performance standard.

(2) Division (D)(1) of this section does not apply if the claimant establishes, by a preponderance of the evidence, that the manufacturer or supplier of the product other than a drug or device fraudulently and in violation of applicable government safety and performance standards, whether or not designated as such by the government, withheld from an applicable government agency information known to be material and relevant to the harm that the claimant allegedly suffered or misrepresented to an applicable government agency information of that type.

(E) The bifurcated trial provisions of division (B) of section 2315.21 of the Revised Code, the ceiling on recoverable punitive or exemplary damages specified in division (D)(1) of that section, and the provisions of division (D)(3) of that section apply to awards of punitive or exemplary damages under this section.

1987 H 1, § 3, eff. 1-5-88.

West's Oregon Revised Statutes Annotated

Title 3. Remedies and Special Actions and Proceedings

Chapter 30. Actions and Suits in Particular Cases

Product Liability Actions

→30.927. Drug manufacturer liability for punitive damages; exceptions

(1) Where a drug allegedly caused the plaintiff harm, the manufacturer of the drug shall not be liable for punitive damages if the drug product alleged to have caused the harm:

(a) Was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal Food and Drug Administration under the Federal Food, Drug and Cosmetic Act or the Public Health Service Act; or

(b) Is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations.

(2) Subsection (1) of this section does not apply if the plaintiff proves, in accordance with the standard of proof set forth in ORS 30.925 (1), that the defendant, either before or after making the drug available for public use, knowingly in violation of applicable federal Food and Drug Administration regulations withheld from or misrepresented to the agency or prescribing physician information known to be material and relevant to the harm which the plaintiff allegedly suffered.

(3) Nothing contained in this section bars an award of punitive damages where a manufacturer of a drug intentionally fails to conduct a recall required by a valid order of a federal or state agency authorized by statute to require such a recall.

(4) For the purposes of this section, the term "drug" has the meaning given to the term in section 1201 (g)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 321(g)(1).

Laws 1987, c. 774, § 5.

West's Utah Code Annotated
Title 78. Judicial Code
Part II. Actions, Venue, Limitation of Actions
Chapter 18. Punitive Damages Awards

§ 78-18-2. Drug exception

(1) Punitive damages may not be awarded if a drug causing the claimant's harm:

(a) received premarket approval or licensure by the Federal Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. Section 301 et seq. or the Public Health Service Act, 42 U.S.C. Section 201 et seq.;

(b) is generally recognized as safe and effective under conditions established by the Federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations.

(2) This limitation on liability for punitive damages does not apply if it is shown by clear and convincing evidence that the drug manufacturer knowingly withheld or misrepresented information required to be submitted to the Federal Food and Drug Administration under its regulations, which information was material and relevant to the claimant's harm.

Laws 1989, c. 237, § 2.